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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,298	04/07/2004	John Sefton	17224CON (AP)	7456

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EXAMINER	
BADIO, BARBARA P	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
09/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/820,298	SEFTON, JOHN	
	Examiner	Art Unit	
	Barbara P. Badio	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-6 and 10-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-6 and 10-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

First Office Action on the Merits of a RCE

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after a decision by the Board of Patent Appeals and Interferences, but before the filing of a Notice of Appeal to the Court of Appeals for the Federal Circuit or the commencement of a civil action. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on August 24, 2009 has been entered.

Specification

2. The use of the trademarks “Tazorac”, “Synalar”, “Elocon”, “Lidex”, “Maxiflor”, “Cultivate”, “Diprosone”, “temovate” and “Valisone” have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1, 4-6 and 10-14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,974,807. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass treatment of proliferative skin diseases by administration of tazarotene and a high potency corticosteroid. Unlike the copending application, the instant claims encompass a broader genus of corticosteroids. However, the instant claims recite corticosteroids such as mometasone furoate, betamethasone valerate and flucinonide (see instant claims 1, 5, 10 and 14) and, thus, selection of a high-potency corticosteroid as recited by the copending application is prima facie obvious based on the instant claims.

Claim Objections

5. Claims 4 and 5 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The instant claims recite "alclometasone dipropionate" not encompassed by parent claim 1.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 4-6 and 10-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims recite "1.0% tazarotene". The present specification discloses:

> The percentage by w/w of the active ingredient, i.e. tazarotene herein utilized ranges from about 0.01% to about 15% of the pharmaceutical preparation, preferably from about 0.1% to about 2% and in these preparations the aforesaid pharmaceutical carrier for topical application constitutes a major amount of the said preparation.

(see page 5, lines 19-23 of the present specification). There is mention of a composition comprising 1.0% tazarotene. Applicant's attention is directed to MPEP § 706.03(o).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1, 6, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto (5,236,906) and Nagpal et al. (5,650,279) in combination.

Yamamoto teaches it is known in the art to use adrenocortical hormones, such as fluocinolone, fluocinolone acetonide, betamethasone valerate and clobetasol propionate, in the treatment of skin diseases such as psoriasis and atopic dermatitis (col. 1, line 11 - col. 2, line 55).

Nagpal et al. teaches it is known in the art to use tazarotene in the treatment of psoriasis (col. 1, lines 42-47).

The instant claims differ from the cited references by reciting the combined use of a corticosteroid and tazarotene in the treatment of skin diseases such as psoriasis. However, it is known in the art as indicated above to use each of the recited compound in the treatment of psoriasis. The combination of two compounds/compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose would have been obvious to one having ordinary skill in the art at the time of the present invention. *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980). Thus, the claimed composition is prima facie obvious based on the combined teachings of the above references. The ordinary artisan in the art at the time of the present invention would have been motivated to use combination treatment for a number of reasons including the reduction of the adverse effect of each of the compound utilized.

10. Claims 1, 6, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (5,874,074) or Sequeira et al. (4,775,529) and Nagpal et al. (5,650,279) in combination.

Each of Smith and Sequeira et al. teach the use of corticosteroids, such as betamethansone dipropionate and mometasone furoate in the treatment of psoriasis (see '074, col. 4, lines 47-67; '529, col. 1, lines 36-63).

Nagpal et al. teaches it is known in the art to use tazarotene in the treatment of psoriasis (col. 1, lines 42-47).

The instant claims differ from the cited references by reciting the combined use of a corticosteroid and tazarotene in the treatment of skin diseases such as psoriasis. However, it is known in the art as indicated above to use each of the recited compound in the treatment of psoriasis. The combination of two compounds/compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose would have been obvious to one having ordinary skill in the art at the time of the present invention. *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980). Thus, the claimed composition is prima facie obvious based on the combined teachings of the above references. The ordinary artisan in the art at the time of the present invention would have been motivated to use combination treatment for a number of reasons including the reduction of the adverse effect of each of the compound utilized.

Other Matters

11. Typographical errors are noted in claims 1 (see "s**S**elected") and claim 14 (see "wherein the **1** corticosteroid"). Correction is required.

Telephone Inquiry

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Barbara P. Badio/
Primary Examiner, Art Unit 1612